

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AMICUS THERAPEUTICS US, LLC and  
AMICUS THERAPEUTICS, INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.  
and TEVA PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 22-1461 (CJB)  
(Consolidated)

**[PROPOSED] FINAL PRETRIAL ORDER**

This matter comes before the Court at a pretrial conference held pursuant to Rule 16 of the Federal Rules of Civil Procedure. Trial is scheduled to begin on September 29, 2025 at 9:00 a.m. D.I. 196 at 4. In advance of the pretrial conference, counsel for Plaintiffs Amicus Therapeutics US, LLC and Amicus Therapeutics, Inc. (collectively, “Amicus”) and Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, “Aurobindo”) submit this Joint Proposed Pretrial Order governing trial of this action pursuant to Federal Rule of Civil Procedure 16, District of Delaware Local Rule 16.3, and the Scheduling Order (D.I. 196).

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## **I. Nature of the Case**

1. This is a consolidated civil action for patent infringement against Aurobindo. This action was filed based on Aurobindo's filing of an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking to market a generic version of Galafold<sup>®</sup> (migalastat) capsules prior to the expiration of Amicus's U.S. Patent No. 11,633,388 ("the '388 Patent"), U.S. Patent No. 12,042,490 ("the '490 Patent"), and U.S. Patent No. 11,833,164 ("the '164 Patent") (collectively, the "Asserted Patents"). To narrow the disputes for trial, Aurobindo has stipulated that its migalastat capsules will infringe Claims 8 and 36 of the '388 Patent, Claim 9 of the '490 Patent, and Claims 23, 24, 25, 26, and 27 of the '164 Patent (collectively, the "Asserted Claims"), to the extent that any of the Asserted Claims are not invalid. D.I. 191 at 2; D.I. 196 at 2. Accordingly, the only remaining disputes for trial in this matter are whether Aurobindo has proven that the Asserted Claims are invalid. As discussed *infra* in Section XVII and Exhibit 15 (Amicus's Motion in Limine No. 1), Amicus's position is that the only invalidity dispute for trial is whether the Asserted Claims are invalid under 35 U.S.C. § 103 and that Aurobindo cannot present a § 101 defense at trial. Aurobindo's position is that it intends to proceed with its invalidity defenses under both 35 U.S.C. §§ 101 and 103. Aurobindo's motion for summary judgment of invalidity of all Asserted Patents due to alleged patent ineligibility under §101 also is pending before the Court. D.I. 223, 226, 230, 231, 234.

2. On June 13, 2024, Amicus filed its Third Amended Consolidated Complaint for Patent Infringement of the claims of the '388 Patent in Civil Action No. 22-1461 (CJB). D.I. 145. On June 13, 2024, Amicus filed a Complaint for patent infringement of the claims of the '164 Patent in Civil Action No. 24-698 (CJB). D.I. 1. On December 6, 2024, Amicus filed a Complaint for Patent Infringement of the claims of the '490 Patent in Civil Action Case No. 24-1331. D.I. 1. These actions have been consolidated under lead action C.A. No. 22-1461 (CJB).

3. On July 11, 2024, Aurobindo filed its Answer to Amicus’s Third Amended Consolidated Complaint. D.I. 154.

4. The 30-month stay of FDA approval for Aurobindo’s ANDA at issue in this case expires on February 10, 2026.

**A. Parties**

**1. Amicus**

5. Amicus Therapeutics US, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its corporate headquarters at 3675 Market Street, Philadelphia, PA 19104.

6. Amicus Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters at 3675 Market Street, Philadelphia, PA 19104.

7. Amicus is the holder of New Drug Application No. 208623 for Galafold<sup>®</sup> capsules, 123 mg, which was granted Subpart H, Accelerated Approval by FDA on August 10, 2018, for the treatment of Fabry disease for patients with certain genetic mutations.

8. Amicus is the owner of all rights, title, and interest in the ’388 Patent, the ’490 Patent, and the ’164 Patent. Aurobindo does not contest that Amicus is the owner of all rights, title, and interest in the Asserted Patents.

**2. Aurobindo**

9. Defendants are Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (together, “Aurobindo”). Aurobindo is represented by R. Touhey Myer, Timothy H. Kratz, George J. Barry III, and Michael P. Hogan of Kratz & Barry LLP.

10. Aurobindo Pharma Ltd. is a limited company organized under the laws of India with a place of business located at, inter alia, Plot No. 2, Maitrivihar, Ameerpet, Hyderabad—

500038, Telangana, India, and Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Randa Reddy District, Hyderabad—500032, Telangana, India.

11. Aurobindo Pharma USA is a corporation organized under the laws of the state of Delaware with a place of business located at 279 Princeton Hightstown Road, East Windsor, NJ 08520.

## **II. Jurisdiction and Standing**

12. This is an action for patent infringement, arising under the patent laws of the United States, Title 35, Section 101, *et seq.*, as well as the Hatch-Waxman Act, 21 U.S.C. § 355, against Aurobindo as a result of its ANDA filing related to a generic version of Galafold®.

13. Subject matter jurisdiction of the Court is not disputed and is based on the patent laws of the United States Code, Title 35, Section 101, *et seq.*, 35 U.S.C. §§ 271, *et seq.*, and 28 U.S.C. §§ 1331 and 1338.

14. Personal jurisdiction is not contested for purposes of this action.

15. Venue is proper in this judicial district under 28 U.S.C. § 1400(b). No party contests venue.

16. Amicus has standing as the record owner of the Asserted Patents. Aurobindo does not dispute Amicus's standing. Aurobindo agrees that Amicus need not present proof of standing at trial.

## **III. Uncontested Facts**

17. The parties stipulate to and admit the facts listed in the Joint Statement of Uncontested Facts attached hereto as **Exhibit 1**. The parties agree that these stipulated facts require no proof at trial and will become part of the evidentiary record in this case.

#### **IV. Disputed Facts**

18. Amicus's Statement of Contested Issues of Fact that remain to be litigated is included in the attached **Exhibit 2**.

19. Aurobindo's Statement of Contested Issues of Fact that remain to be litigated is included in the attached **Exhibit 3**.

20. If any statement in a party's statement of contested issues of fact should be properly considered an issue of law, then such statement shall be so considered as an issue of law.

#### **V. Issues of Law**

21. Amicus's Statement of Contested Issues of Law that remain to be litigated is included in the attached **Exhibit 4**.

22. Aurobindo's Statement of Contested Issues of Law that remain to be litigated is included in the attached **Exhibit 5**.

23. If any statement in a party's statement of contested issues of law that remain to be litigated should properly be considered an issue of fact, then such statement shall be so considered as an issue of fact.

#### **VI. Brief Statement of Intended Proofs**

24. In support of its claims and defenses and in addition to the facts not in dispute, Amicus expects to offer the proofs attached as **Exhibit 6**.

25. In support of its claims and defenses and in addition to the facts not in dispute, Aurobindo expect to offer the proofs attached as **Exhibit 7**.

## **VII. Witnesses**

### **A. List of Witnesses Amicus and Aurobindo Expect to Call**

26. Amicus's list of witnesses it may call live at trial and by deposition, together with Aurobindo's objections, is attached as **Exhibit 8**. For Amicus's witnesses that will not appear live but will appear only by deposition, Amicus's list of deposition designations, together with Aurobindo's counter-designations and the parties' respective objections, is identified in attached **Exhibit 9**. Aurobindo's list of witnesses it may call live at trial and by deposition, together with Amicus's objections, is attached as **Exhibit 10**. For Aurobindo's witnesses that will not appear live but will appear only by deposition, Aurobindo's list of deposition designations, together with Amicus's counter-designations and the parties' respective objections, is identified in attached **Exhibit 11**.

27. Any witness not listed in **Exhibits 8 or 10** will be precluded from testifying at trial. The listing of a witness on a party's witness list does not require the party to call that witness to testify and does not imply or establish that the listing party has the power to compel the live testimony of that witness or make that witness available to the opposing party. The parties reserve the right to call one or more additional witnesses whose testimony is necessary to establish admissibility of any trial exhibit, if the admissibility of the exhibit is challenged by an opposing party. The parties' witness lists represent the parties' good faith understanding and expectation about which witnesses are expected to be called live in person, or by deposition, at trial. To the extent that a witness's circumstances change, or a witness otherwise becomes unavailable for trial, each party reserves the right to call that witness by deposition to the extent permitted under the Federal Rules of Civil Procedure and the Federal Rules of Evidence and subject to resolution of objections by the other party.

28. Fact witnesses appearing in person (other than a party's corporate representative) shall be sequestered. Expert witnesses need not be sequestered. During adjournments in the trial of no more than five days, including breaks during the trial day and overnight, the offering party may discuss with a witness his or her testimony on direct examination until the witness is passed for cross-examination and cross-examination has commenced, but is prohibited from discussing with the witness his or her testimony once cross-examination has begun. Once cross-examination of the witness is concluded, the offering party may discuss with the witness his or her testimony on re-direct examination.

**B. Disclosure of Witnesses to Be Called at Trial**

29. Each party shall identify by electronic mail a good faith order of all of their live trial witnesses by 6:00 p.m. ET one week ahead of the start of trial. Additionally, the parties agree they will timely notify the other party if there are any anticipated changes to the order of live trial witnesses after this disclosure and before the start of trial.

30. Each side shall serve on opposing counsel by electronic mail all trial witnesses (whether live or by deposition testimony) in the order that the side expects to call them by **6:00 p.m. ET two calendar days before the witness is intended to be called** (e.g., notice must be given by 6:00 p.m. on Monday for witnesses to be called on Wednesday). The party receiving identification of the witnesses will inform the party identifying the witnesses of any objections to such witnesses via email **by 8:00 p.m. ET that same evening**, and the parties will meet and confer to resolve any objections **by 9:00 p.m. ET that same evening**. If good faith efforts to resolve any objections fail, the party objecting may bring its objections to the Court's attention the next morning before the start of the trial day.

**C. Testimony by Deposition**

31. This pretrial order contains the maximum universe of deposition designations, counter-designations, and objections to admission of deposition testimony in **Exhibits 9 and 11**; none of the foregoing shall be supplemented without approval of all parties or leave of the Court, on good cause shown.

32. Unless otherwise agreed between the parties, the party offering deposition testimony shall serve on opposing counsel by electronic mail the deposition testimony (i.e., transcript page and line numbers) to be offered from previously exchanged designations **by 6:00 p.m. ET five calendar days prior to the testimony being offered** into the record. The party receiving the designations shall inform the opposing party of any objections and counter-designations **by 6:00 p.m. ET four calendar days prior to the testimony being offered** into the record, and **by 6:00 p.m. ET the following day (three calendar days prior to the testimony being offered into the record)**, the parties shall meet and confer to resolve any objections to designated testimony to permit sufficient time to prepare any necessary video/DVD of the testimony.

33. If there are objections that remain to be resolved, the party calling the witness by deposition shall, **no later than two calendar days before the witness is to be called at trial**, submit, on behalf of all parties: (i) a copy of the entire deposition testimony of the witness at issue, clearly highlighting the designations, counter-designations, and pending objections; and (ii) a cover letter clearly identifying the pending objections as well as a brief indication (i.e., no more than one sentence per objection) of the basis for the objection and the offering party's response to it. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of the deposition testimony or waiver of objection to the use of the deposition testimony.

34. All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is read or viewed at trial. Prior to the introduction of deposition designations or counter-designations, counsel for the introducing party may provide a short introduction to the Court about the identity of the witness and brief, neutral introduction for the purpose of the designations that is agreed upon by the parties, which introduction the parties agree is not evidence and the time for which will be charged against that party.

35. When the witness is called to testify by deposition at trial, the party calling the witness shall provide the Court with two copies of the transcript of the designations and counter-designations that will be read or played. The parties will be charged for all time that elapses from the time the witness is called until the next witness is called, according to the proportions to be provided by the parties. To the extent deposition designations are read or played in open court, each side will be charged the time taken to read or play its designations (or counter-designations). Specifically, any affirmative designations offered by a party will count against that party's trial presentation time, whereas any counter-designations by the other party will count against the party who made the counter-designations. The time charged for designations played by video will be measured by the time on the video. The time charged for designations read aloud will be measured by the proportion of the number of lines of testimony for its designations to the total number of lines of testimony read. The parties are not required to designate deposition testimony that an expert will rely on during their trial testimony so long as that deposition testimony was cited in that expert's report.

36. If a party decides to play some but less than all of the designated testimony for a witness at trial, the opposing party may use such dropped testimony as counter-designations to

the extent the usage of such testimony in such manner is otherwise consistent with Federal Rule of Evidence 106, Federal Rule of Civil Procedure 32, and any other applicable Federal Rule of Evidence or Rule of Civil Procedure. If applicable, a party's designation of a page and line from a particular transcript shall be automatically deemed to include any errata indicated for that page and line in the attached errata sheets.

37. To the extent that deposition designations or counter-designations are admitted into evidence, they must be either played by video or read in open court. If a party opts to introduce deposition testimony, any counter-designation of that same witness's testimony must be admitted in the same medium, and the testimony designated by both sides will be played or read consecutively in the sequence in which the testimony was originally given at deposition. If an exhibit is referenced in a deposition designation, the exhibit is admitted into evidence if it is included on any party's trial exhibit list and is not otherwise objected to, subject to Section VIII.

**D. Impeachment with Prior Inconsistent Testimony**

38. The above procedures regarding deposition designations do not apply to portions of deposition transcripts and/or video of a witness used for impeachment. Any deposition testimony of a witness may be used at trial for the purpose of impeachment of that witness, regardless of whether a party specifically identified that testimony on its list of deposition designations, if the testimony is otherwise competent for such purpose.

**E. Objections to Expert Testimony**

39. The parties request that the Court rule at trial on objections to expert testimony as outside the scope of prior expert disclosures, taking time from the losing parties' trial presentation to argue and decide such objections.

## VIII. Exhibits

### A. Trial Exhibits

40. The joint list of pre-marked trial exhibits that may be offered by any party is attached as **Exhibit 12**. The parties' joint trial exhibits will be identified by JTX numbers.

41. The list of pre-marked exhibits that may be offered by Amicus, with Aurobindo's objections thereto, is attached as **Exhibit 13**. Amicus's trial exhibits will be identified with PTX numbers.

42. The list of pre-marked exhibits that may be offered by Aurobindo, with Amicus's objections thereto, is attached as **Exhibit 14**. Aurobindo's trial exhibits will be identified with DTX numbers.

43. Amicus and Aurobindo each reserve the right to offer exhibits set forth on the others' exhibit list, even if not set forth on their own exhibit list, and each party reserves the right to raise objections to the use of the exhibit by the offering party, even if the exhibit is on the opposing party's exhibit list. All objections to such exhibits are preserved.

44. The listing of an exhibit on a party's trial exhibit list does not constitute an admission as to the relevance or admissibility of that trial exhibit. Each party reserves the right to object to the relevance or admissibility of any evidence offered by another party at the time such evidence is offered and in view of the specific context in which such evidence is offered. The parties agree that any description of a document on an exhibit list is provided for convenience only and shall not be used as an admission or otherwise as evidence regarding the document. Nothing herein shall be construed as a stipulation or admission that a document is entitled to any weight in deciding the merits of this case.

45. This pretrial order contains the maximum universe of exhibits to be used in any party's case-in-chief or rebuttal case, as well as all objections to the admission of such exhibits,

neither of which shall be supplemented without approval of all parties or leave of the Court, on good cause shown. Exhibits not listed will not be admitted unless good cause is shown.

Notwithstanding the foregoing, the parties reserve the right to offer additional exhibits for impeachment purposes.

46. No exhibit will be admitted unless offered into evidence through a witness (either live or by designation), who must at least be shown the exhibit. At some point before the completion of the witness' testimony, any party that has used an exhibit with the witness and wishes that exhibit to be admitted into evidence must formally move the exhibit into evidence, by exhibit number.

47. Any trial exhibit that was produced in discovery by a party and that on its face appears to have been authored by an employee, officer, or agent of the party that produced such document, will be deemed to be a true and correct copy of a document maintained in that producing party's files as of the date of the party's document collection under Federal Rule of Evidence 901. No foundation need be laid for the authenticity of such documents at trial. For clarity, this provision does not obviate the need to otherwise lay the proper foundation for admissibility of a document or of testimony about that document (e.g., relevance or personal knowledge of a fact witness).

48. Exhibits not objected to will be received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony, provided they are shown to a witness.

49. On or before the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

50. The parties will meet and confer each day to discuss the list of admitted exhibits used during that trial day. The parties will jointly coordinate with Court staff to ensure the Court and all parties have an accurate list of admitted exhibits, and in the event of a dispute, timely raise any issues in the morning.

**B. Stipulations Concerning Trial Exhibits**

51. Any exhibit, once admitted, may be used equally by each party for any proper purpose in accordance with the Federal Rules of Evidence.

52. Legible copies of documents may be offered and received into evidence to the same extent as an original. The parties may substitute pre-marked exhibits identified on **Exhibits 12–14** with color copies and/or more legible versions provided that the content and text is identical to that which was previously identified in **Exhibits 12–14** and previously exchanged among the parties in preparing this Joint [Proposed] Pretrial Order. For particularly voluminous documents (e.g., patent application file histories, New Drug Applications, Abbreviated New Drug Applications, and Drug Master Files), the parties may use excerpts of the documents identified on **Exhibits 12–14** provided: (i) such excerpts do not mischaracterize or misrepresent the contents of the document as a whole; (ii) such excerpts are disclosed in accordance with the procedures set forth below, in Section VIII.C.1; and (iii) the other party is permitted to add a reasonable number of pages to the intended excerpt necessary to provide adequate context and completeness for the intended excerpt.

**C. Procedure for Trial Exhibit Disclosure**

**1. Exchange of Exhibits**

53. Each party shall provide by electronic mail to opposing counsel a list of all exhibits (by exhibit number) that the party intends to use in direct examination of witnesses, **by 6:00 p.m. ET one calendar day before they will be used** at trial. For example, a listing of all

exhibits intended for use during direct examination of witnesses on Monday, September 29, 2025, would be exchanged by email before 6:00 p.m. ET on Sunday, September 28, 2025. A party seeking to substitute a pre-marked exhibit with a color and/or more legible version of the same shall provide such substitutions at this time. Notwithstanding the foregoing, each party reserves the right to amend or supplement the list with a reasonable number of exhibits provided such exhibits are promptly identified.

## **2. Objections to Exhibits**

54. The party receiving identification of exhibits intended for use in direct examination of witnesses pursuant to the previous paragraph shall inform the party identifying the exhibits of any objections **by 8:00 p.m. ET one calendar day before they will be used**, and the parties shall meet and confer as soon as possible thereafter, but **by no later than 9:00 p.m. ET the same day** to resolve such objections. Any unresolved objections shall be brought to the Court's attention for resolution no later than the start of the trial day on which the exhibit is intended to be used.

## **3. Courtesy Copies of Exhibits**

55. Prior to the start of direct examination of a particular witness, the party conducting the direct examination will provide the other party with two copies of binders containing all exhibits and demonstrative exhibits that they intend to use with that witness on direct examination and will provide all required copies to the Court. The parties agree that this provision does not require the advanced disclosure of exhibits to be used to impeach or on cross-examination of any witness, provided such exhibits were identified on a party's exhibit list (i.e., **Exhibits 12-14**) unless used solely for purposes of impeachment. However, prior to the start of the cross-examination of any witness, the parties agree to provide the other with two copies of

witness binders that contain all of the exhibits expected to be used on cross-examination of that witness and will provide all required copies to the Court.

**D. Demonstrative Exhibits**

56. The parties may use demonstrative exhibits, which do not need to be identified on their respective lists of trial exhibits. Amicus's demonstrative exhibits will be identified with PDX numbers. Aurobindo's demonstrative exhibits will be identified with DDX numbers.

57. Each demonstrative exhibit shall identify by exhibit number all trial exhibits that form the basis of the demonstrative exhibit. Such identified trial exhibits referenced in the demonstrative exhibit and shown to a witness shall be offered into evidence during or at the conclusion of the examination for the witness with whom the demonstratives were used.

**1. Demonstratives for Opening Statements**

58. Trial exhibits and demonstrative exhibits to be used with opening statements shall be exchanged via electronic mail **by 4:00 p.m. ET one calendar day before opening statements**. The materials to be exchanged for opening statements will be the same as for all other exchanges for trial and demonstrative exhibits. For example, trial and demonstrative exhibits intended for use with opening statements on Monday, September 29, 2025, would be exchanged by email before 8:00 a.m. on Sunday, September 28, 2025. Any objections shall be exchanged **by 6:00 p.m. ET on the day prior to opening statements**, and the parties shall meet and confer as soon as possible thereafter but **by no later than 7:00 p.m. ET on the day prior to opening statements** to resolve such objections.

**2. Demonstratives for Closing Arguments**

59. If the Court prefers closing arguments, the parties may use demonstratives for closing arguments. The parties do not need to exchange closing argument demonstratives. The

parties propose scheduling closing arguments at the Court's convenience, either before or after post-trial briefing is complete.

### **3. Exchange of Witness Demonstratives**

60. Each party will exchange copies of demonstrative trial exhibits expected to be used during the direct examination of a witness by email **by 6:00 p.m. ET one calendar day before their intended use.**

61. Any objections to demonstrative exhibits will be provided **no later than 8:00 p.m. ET on the day of receipt**, and the parties shall meet and confer as soon as possible thereafter but **by no later than 9:00 p.m. ET on that same day** to resolve such objections. If the parties' meet and confer session causes the party offering the demonstrative exhibit to make edits of substance, that party shall disclose the revised exhibit to the objecting party as soon as possible.

62. If good faith efforts to resolve objections to demonstrative exhibits fail, the objecting party shall bring its objections to the Court's attention prior to the morning of the trial day when the demonstrative is expected to be used. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

63. The party seeking to use a demonstrative will provide a color representation of the demonstrative to the other side in PDF form. For video or animations, the party seeking to use the demonstrative will provide it to the other side in an appropriate electronic format to view the video or animation. For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide a color representation as a PDF of 8.5 x 11 copies of the exhibits.

64. The parties need not exchange in advance of their use any demonstrative exhibits created during testimony or demonstratives to be used solely on cross-examination. In addition,

enlargements or highlights of exhibits or parts of exhibits or testimony created live during the witness's testimony are not required to be provided to the other side in advance of their use.

65. For the avoidance of doubt, only a demonstrative exhibit that falls into one of the following categories is not required to be provided to the other side in advance of its use: (a) a copy of a single trial exhibit or part of a single trial exhibit, or a blow-up or highlighting of a single trial exhibit or part of a single trial exhibit, or (b) a blow-up or highlighting of a single deposition or trial transcript or part of a single deposition or trial transcript.

#### **IX. Damages**

66. Amicus does not seek damages at this time, as there has been no commercial launch of Aurobindo's ANDA product. Amicus reserves the right to seek attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 285. Amicus reserves the right to seek damages if Aurobindo commercially manufactures, uses, sells, offers to sell, or imports into the United States its accused ANDA product prior to the expiration of the Asserted Patents.

#### **X. Motions *In Limine***

67. Amicus's motions *in limine* and related briefing are attached in **Exhibits 15–17**.

68. Aurobindo's motions *in limine* and related briefing are attached in **Exhibits 18–19**.

#### **XI. Discovery**

69. Each party has completed discovery.

#### **XII. Non-Jury Trial – Post-Trial Briefing**

70. Thirty days after trial, (i) Aurobindo shall file a post-trial brief on issues of invalidity and (ii) Amicus shall file a post-trial brief on secondary considerations of non-obviousness. Thirty days after opening briefs are filed, (i) Aurobindo shall file a post-trial brief responding to issues as to secondary considerations of non-obviousness and (ii) Amicus shall file

a post-trial brief responding to issues of invalidity. [Amicus's position: Reply briefs are not necessary as validity, including any secondary considerations of non-obviousness, should be adequately addressed in the initial and responsive briefs. Each party shall have 60 total pages combined to allocate between their initial and responsive briefs. If, however, the Court prefers for the parties to file reply briefs, Amicus proposes that the length and timing of such reply briefs be at the Court's convenience.<sup>1</sup>] [Aurobindo's position: Fifteen days after responsive briefs are filed, (i) Aurobindo shall file a post-trial reply brief on issues of invalidity and (ii) Amicus shall file a post-trial reply brief on secondary considerations of non-obviousness. Each party shall have 75 total pages combined to allocate between their initial, responsive, and reply briefs.]

71. Along with their initial briefs, each party shall provide proposed Findings of Fact, separately stated in numbered paragraphs, constituting a detailed listing of the relevant material facts the party believes it has proven, in a simple narrative form, along with citations to the record. With their responsive briefs, each party shall provide responsive Findings of Fact. Each party shall have 60 total combined pages to allocate between their initial and responsive proposed Findings of Fact. No separate Conclusions of Law shall be filed.

72. Only admitted trial exhibits and demonstratives used at trial and lodged into the record may be relied upon in post-trial briefing.

73. No appendices shall be submitted with any post-trial briefs.

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<sup>1</sup> Amicus respectfully submits that post-trial reply briefs are not necessary and allowing such briefing may invite gamesmanship of reserving for reply arguments that should be made in a full and fair opening, particularly in light of the known trial record. Aurobindo bears the burden of proof on invalidity and will have an opportunity to present its full argument in its initial brief, as well as present its full argument on secondary considerations in its responsive brief.

### **XIII. Length of Trial**

74. The trial will be timed, and the parties request [Amicus's position: 11 hours per side<sup>2</sup>; Aurobindo's position: 9 hours per side] for their trial presentation including opening statements [Amicus's position: and, if preferred by the Court, closing arguments; Aurobindo's position: with closing statements not counting for trial time]. The parties estimate that their trial presentations will take [Amicus's position: 4 days; Aurobindo's position: 3 days]. Time will be charged to a party for its opening statement, direct and redirect examinations of witnesses it calls, cross-examination of witnesses called by any other party, closing argument, its argument on any motions for judgment as a matter of law, and all sides' argument on objections a party raises to another party's exhibits and demonstrative exhibits. For any arguments related to objections a party raises to another party's exhibits and demonstrative exhibits, time charged shall be split equally between the parties.

75. The parties will keep a running total of trial time used by counsel and report to the Courtroom Deputy what their running total is for each trial day by 9:00 a.m. on the following trial day. If any party uses all of its allotted trial time, the Court will terminate that party's trial presentation.

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<sup>2</sup> Amicus respectfully requests 11 hours per side at trial, or a 4-day trial. *See* <https://www.ded.uscourts.gov/sites/ded/files/chambers/CJB-PatentPTO.pdf> ("In a typical bench trial, each day will involve between 6 and 7 hours of trial time."). The trial will involve testimony from four fact witnesses and three expert witnesses. *See* Exhibit 11. And the trial time will encompass opening and closing statements. Amicus's proposal is less than the 5-day trial in the Scheduling Order. *See* D.I. 196 at 4.

#### **XIV. Motions for Judgment as a Matter of Law**

76. If a party elects to move for judgment on partial findings pursuant to Federal Rule of Civil Procedure 52(c), it may do so orally at the conclusion of a party's case or at the close of all evidence.

#### **XV. Desired Amendments to the Pleadings**

77. The parties do not believe any amendments to the pleadings are necessary.

#### **XVI. Order of Proof**

78. The following order of proof will apply to trial:

- a. Opening statements will be delivered in the following order: Aurobindo followed by Amicus;
- b. Aurobindo will present its case-in-chief on invalidity;
- c. Amicus will present its rebuttal to invalidity, including as to secondary considerations of non-obviousness;
- d. Aurobindo will present its rebuttal only to evidence of secondary considerations of non-obviousness; and
- e. If the Court prefers closing arguments, closing arguments will be delivered in the following order: Aurobindo followed by Amicus, and, if the Court prefers, with brief reply by Aurobindo. The parties propose scheduling closing arguments at the Court's convenience, either before or after post-trial briefing is complete.

#### **XVII. Additional Matters**

79. Pursuant to the parties' meet and confer on August 4, 2025, Aurobindo stipulates that its expert, Dr. Medin, will not provide any opinion at trial that the Asserted Claims are independently invalid under 35 U.S.C. § 112.

80. Amicus's statement of miscellaneous issues is below: Amicus respectfully submits that Aurobindo cannot present a section 101 defense at trial. First, in its motion for summary judgment, Aurobindo failed to meet its burden as a matter of law under step one of *Alice*. There is thus no remaining issue for trial. Second, even if the Court were to find that Aurobindo met its burden under step one of *Alice*, there is no dispute for trial as to step two. Aurobindo has waived its ability to offer evidence at trial on step two of *Alice* because it did not disclose any expert opinions as to ineligibility under section 101, let alone what was well-understood, routine, and conventional under step two of *Alice*. Aurobindo therefore has no means to offer such evidence at trial. Amicus's Motion *in Limine* No. 1 (Exhibit 15) further requests that Aurobindo be precluded from offering at trial argument and evidence regarding invalidity under section 101.

81. Aurobindo's statement of miscellaneous issues is below: Amicus's statement regarding Aurobindo's defense of invalidity under 35 U.S.C. § 101 is mistaken. To the extent the Court has not granted Aurobindo's motion for summary judgment, Aurobindo intends to proceed with its § 101 defense at trial and reserves the right to rely on all evidence and testimony admitted at trial. Aurobindo's statements regarding expert opinion testimony as they may related to § 101 pertained solely to Aurobindo's motion for summary judgment. Aurobindo's reply to Amicus's *Motion In Limine* No. 1 is also attached to this PreTrial Order at Exhibit 15.

#### **XVIII. Certification of Settlement Discussions**

82. The parties have engaged in good-faith efforts to explore resolution of this case by settlement. To date, the parties have not reached agreement.

**IT IS HEREBY ORDERED** that this Final Pretrial Order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

DATED: \_\_\_\_\_

\_\_\_\_\_  
United States District Judge

APPROVED AS TO FORM AND  
SUBSTANCE:

\_\_\_\_\_  
ATTORNEY FOR AMICUS

\_\_\_\_\_  
ATTORNEY FOR AUROBINDO

Respectfully Submitted,

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August 15, 2025